

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year) 16 NOV 2005		
Applicant's or agent's file reference GENN01011WO0		
FOR FURTHER ACTION See paragraph 2 below		
International application No. PCT/US04/42027	International filing date (day/month/year) 13 December 2004 (13.12.2004)	Priority date (day/month/year) 12 December 2003 (12.12.2003)
International Patent Classification (IPC) or both national classification and IPC IPC(7): G01N 33/48 and US Cl.: 702/19		
Applicant GNI LTD.		

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Date of completion of this opinion 19 October 2005 (19.10.2005)	Authorized officer: <i>Valeria Bell-Harr</i> Jerry Lin Telephone No. (571) 272 1600
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Form PCT/ISA/237 (cover sheet) (April 2005)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US04/42027

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
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Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>4-11</u>	YES
	Claims <u>1-3, 12-17</u>	NO
Inventive step (IS)	Claims <u>4-11</u>	YES
	Claims <u>1-3, 12-17</u>	NO
Industrial applicability (IA)	Claims <u>1-17</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-3 and 12-17 lack novelty under PCT Article 33(2) as being anticipated by Imoto et al. (US 20030219764 A1).

Imoto et al. teach a method that includes an inferential model of possible gene networks (Abstract); selecting a biologically relevant subspace of a search space (page 1, paragraph 0007); calculating the optimal solution in the subspace with an algorithm (page 1, paragraph 0009; page 2, paragraph 0011); a Bayesian network estimation model (pages 1-2, paragraph 0010); genes relating to a metabolic pathway of an organism (pages 1-2, paragraph 0010); a scoring function such as BRNC (pages 1-2, paragraph 0010); a storage medium or system (page 20, paragraphs 0288-0294).

Claims 1-3 and 12-17 lack an inventive step under PCT Article 33(3) as being obvious over Imoto et al. (US 20030219764 A1) for the reasons above.

Claims 4-11 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the limitations of the instant claims.

Claims 1-17 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry for the purpose of determine gene relationships.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 4-12 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 4-11 are indefinite for the following reason(s):

Claims 4-11 are indefinite because they contain mathematical equations with undefined variables. For example, in instant claim 4, the variable A, G, g, etc are not defined as to what they represent.

Claim 12 is definite because it unclear to what the abbreviations BRNC, Bde, and MDL refer.